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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Tukanori KIGAWA et al.**

Group Art Unit:

Serial No.: **10/524,114**

Examiner:

Filed: **February 10, 2005**

Confirmation No.:

For: **HUMAN-ORIGIN PROTEINS FORMING DOMAIN AND USE THEREOF**

Attorney Docket Number: **052083**

Customer Number: **38834**

SUBMISSION OF ENGLISH TRANSLATION OF IPER

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

August 17, 2005

Sir:

Submitted herewith is an English translation of the International Preliminary Examination Report for the above-identified U.S. patent application.

If any additional fees are due in connection with this submission, please charge our Deposit Account No. 50-2866.

Respectfully submitted,

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SGA/arf

From the INTERNATIONAL BUREAU

PCTNOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 72.2)

To:

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ACKNOWLEDGED

MAY. - 6. 2005

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IMPORTANT NOTIFICATION

Date of mailing (day/month/year) 28 April 2005 (28.04.2005)	
Applicant's or agent's file reference P02-0086PCT <i>Got - 0005 US. EP</i>	
International application No. PCT/JP2003/010288	International filing date (day/month/year) 13 August 2003 (13.08.2003)
Applicant RIKEN et al	

1. Transmittal of the translation to the applicant.

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority.

2. Transmittal of the copy of the translation to the elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation:

CA, EP

The following elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

JP, US

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report.

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Masashi Honda
Facsimile No.+41 22 740 14 35	Facsimile No.+41 22 338 70 10

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/010288

Box No. 1 Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

- ☐ international search (under Rules 12.3 and 23.1(b))
☐ publication of the international application (under Rule 12.4)
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/010288

Supplemental Box Relating to Sequence Listing

Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:
- a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☒ filed together with the international application in computer readable form
 - ☐ furnished subsequently to this Authority for the purpose of search and/or examination
 - ☐ received by this Authority as an amendment* on _____
2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

* If item 4 in Box No. 1 applies, the listing and /or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP 03/10288

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-20	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims		NO

2. Citations and explanations

Document 1: Nature Genetics, 2000, Vol. 25, pages 160-165

Document 2: WO 00/17355 A2 (Incyte Pharmaceuticals Inc.), 03 March 2000, & EP 1114158 A2 & JP 2002-526076 A

Document 3: WO 01/042453 A1 (Hidekazu HIROAKE), 14 June 2001, & JP 2001-544328 A

Document 4: JP 7-206894 A (Advanced Technology Institute Kabushiki Kaisha), 08 August 1995

Claims 1-8, 10, 11 and 15

The inventions that are set forth in claims 1-8, 10, 11 and 15 do not involve an inventive step in the light of document 1 cited in the international search report.

Document 1 indicates that the cancer suppression gene CYLD from humans comprises three CAP-Gly domains, and illustrates that a CAP-Gly domain is present in the region comprising amino acids 464-554 (the amino acid sequence that is common to SEQ ID NO: 1, 3, 5 and 7) in the CYLD protein (fig. 4).

In addition, it would be obvious to a person skilled in the art to produce a domain by means of recombinant DNA technology in order to analyze the structure of said domain, and it would also be obvious to a person skilled

in the art to identify genes that are related to CAP-Gly domains using the transformed cells that are obtained.

Claims 9 and 12

The inventions that are set forth in claims 9 and 12 do not involve an inventive step in the light of documents 1 and 2 cited in the international search report.

Document 2 discloses the amino acid sequence (SEQ ID NO: 9) and the base sequence (SEQ ID NO: 25) for the human cytoskeleton associated protein (CYSKP) 9, and indicates that said protein contains a CAP-Gly domain (charts 2-3). In addition, document 2 discloses antibodies that specifically bond to partial polypeptides from said protein, as well as agonists and antagonists against said polypeptides.

Consequently, it would be obvious to a person skilled in the art to create antibodies against the CAP-Gly domains that are indicated in document 1, and to screen for ligands (agonists and antagonists) that bond to the CAP-Gly domains.

Claims 13 and 14

The inventions that are set forth in claims 13 and 14 do not involve an inventive step in the light of documents 1 and 2 cited in the international search report.

In the technical field in question, it is common practice to use antibodies in order to determine the quantity of a polypeptide.

Claims 16-19

The invention that is set forth in claims 16-19 does not involve an inventive step in the light of documents 1-3 cited in the international search report.

Document 3 discloses a method that uses the three-

dimensional structural coordinates of a protein or a mutant thereof that contains a PX domain in order to identify, search for, evaluate or design compounds which promote the binding activity of a substance that is capable of binding to the PX domain.

Furthermore, the present invention pertains to computer software for processing information, wherein the information processing method employs the abovementioned technical feature. Information processing methods wherein the procedures for processing information do not differ from the procedures in prior art methods cannot be considered to be novel. Herein, the "information pertaining to the three-dimensional structure," which is indicated in the present application as a feature that differentiates the present invention from the prior art, merely alludes to the content of the data to be processed, and does not indicate a change in the procedures by which a computer processes information; therefore, this difference is not sufficient to establish the novelty of the invention that is set forth in claims 16-19 of the present application.

Consequently, in the light of document 3 it would be obvious to a person skilled in the art to implement the screening method, which has been determined to be obvious on the basis of documents 1 and 2, on a computer.

Claim 20

The invention that is set forth in claim 20 does not involve an inventive step in the light of documents 1 and 4 cited in the international search report.

Document 4 discloses a method for predicting the three-dimensional structure of a target protein on the basis of the coordinates of a reference protein that exhibits a high degree of homology in relation to the target protein.

Furthermore, the present invention pertains to computer software for processing information, wherein the information processing method employs the abovementioned technical feature. Information processing methods wherein the procedures for processing information do not differ from the procedures in prior art methods cannot be considered to be novel. Herein, the "information pertaining to the three-dimensional structure," which is indicated in the present application as a feature that differentiates the present invention from the prior art, merely alludes to the content of the data to be processed, and does not indicate a change in the procedures by which a computer processes information; therefore, this difference is not sufficient to establish the novelty of the invention that is set forth in claim 20 of the present application.

Consequently, in the light of document 4 it would be obvious to a person skilled in the art to estimate the three-dimensional structure of a protein that is similar to the CAP-Gly domain, which is disclosed in document 1, on a computer 4.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/010288

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 03/048341 A2	12 June 2003 (12.06.2003)	03 December 2002 (03.12.2002)	03 December 2001 (03.12.2001)
[E X]			

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

If the inventions that are set forth in claims 16-18 and 20 are understood to pertain to software, then the disclosures of said claims are unclear because they do not directly specify the manner in which the hardware resources and the processing of information by means of software are interrelated (the Japanese Patent Office has determined that the present invention does not correspond to a "creative result of a technical concept utilizing the laws of nature," and as such, does not pertain to a subject matter that can be protected by a patent.

Claims 16-19 disclose the feature of screening for compounds (ligands) that are capable of binding to the CAP-Gly domain by means of a computer. However, the description does not present any experimental results indicating that the ligand candidates which are identified via their atomic coordinates actually exhibit an affinity for bonding to the CAP-Gly domain; therefore, claims 16-19 do not conform to the enabling requirement.

Claim 20 discloses a method for estimating the three-dimensional structure of a protein with an unknown structure, which is similar to the CAP-Gly domain, by means of a computer. However, the description does not make any specific disclosures pertaining to the three-dimensional structure of proteins with an unknown structure; therefore, claim 20 does not conform to the enabling requirement.